

REMARKS

The instant amendment is submitted in order to expedite prosecution. Support for the amendment to the claims directed to the combination of fentanyl and a basic pH adjusting substance can be found in the examples of the application as filed. No new matter is submitted. Entry of the amendment is respectfully requested. The claims have been amended to limit the medicament to fentanyl or its pharmaceutically acceptable salt and to limit the pH adjusting substance to a basic material in an effort to streamline prosecution and receive an early allowance of the claims. It is not Applicants' intention to abandon previously claimed broader subject matter; such claims will be pursued in continuing application(s).

As a preliminary matter, the undersigned would like to thank Examiner Lamm for the courtesies extended by her during a brief telephone interview conducted on June 23, 2005. In particular, the undersigned expressed an intention to file the instant claim amendments in order to expedite prosecution so as to facilitate early allowance of the amended claims.

In the Office Action mailed December 29, 2004, claim 95 was provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-4 of copending Application No. 10/080,016. It is noted that since claims 2-4 have been canceled in said Application, this rejection is moot.

With regard to the significance of the claims in their currently amended form, it is respectfully noted that the art relied on, *Robinson* and *Norling*, do not provide a *prima facie* basis for a rejection. Specifically, the instant claims include both the specific active ingredient, "fentanyl or its pharmaceutically acceptable salt," and a recitation that a base

is to be used to adjust pH. This distinguishing combination of features, in further combination with those already present in the claims as previously explained by Applicants, provide a clear basis for allowance of the claims. Nothing in either reference, taken alone or in combination, teaches or suggests an effervescent tablet for buccal, gingival or sublingual administration of this particular drug using a specific type of pH adjusting substance. Withdrawal of the rejection of the pending amended claims is respectfully requested.

The rejection of claims 22, 23, 25-36, 83-91, 93, 94, 96 and 97 under 35 U.S.C. §103(a) as allegedly being unpatentable over *Robinson et al.*, U.S. 6,071,539 (hereinafter "*Robinson*") has been maintained for the reasons of record. Similarly, claim 95 has been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over *Robinson* in view of *Norling et al.*, U.S. 5,958,458 (hereinafter "*Norling*"), also for reasons of record. These rejections are respectfully traversed.

For purposes of advancing prosecution and in the interest of avoiding a repetitive written record, Applicants reiterate their arguments in the prior responses and rely on the reasons of record in response to the reasons of record advanced by the Office. Additionally, and briefly, however, it is noted that in view of the cancellation of claims, certain of the arguments advanced by the Office are no longer relevant, for example those that rely on the previous recitation in the claims of "a medicament" or of "prochlorperazine." Furthermore, in responding to Applicants' prior arguments, the Office continues to rely on the concept of "inherency" (pages 3 and 4 of the Office Action) although the rejection is based on obviousness. It is accepted praactice that reliance on inherency is only appropriate for a rejection founded on anticipation, 35 U.S.C.

§102, and not under §103(a). In particular, Applicants previously cited cases in support of this distinction. Applicant's arguments based thereon have not been addressed, even though the December 29, 2004 Office Action quotes the language from Applicants' response, specifically, "Moreover, "[t]he mere fact that a certain thing may result from a given set of circumstances is not sufficient [to establish inherency.]", *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993). A retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection. See *In re Newell*, 891 F.2d 899, 901 (Fed. Cir. 1989)." (page 10 of Applicants' response dated October 26, 2004)

Additionally, the last three sentences of the Office's Response to Arguments, page 5 of the Office Action state:

The only difference between the claimed tablet and the Robinson's tablet seems to be in the method of using the tablet. Thus, the claimed tablet is kept in the mouth for a certain period of time, while the Robinson's tablet is swallowed right after it disintegrates. However, such difference is not recited in the instant claims."

With all due respect, this observation and response by the Office does not reflect the previous amendment to the claims in which Applicants explicitly added the following language to the terminal portion of the independent claims:

"said tablet suitable for buccal, sublingual and gingival administration of said medicament across the oral mucosa."

In particular, Applicants explained the significance of this amendment and provided explicit technical support (the art accepted distinction between transmucosal and orogastric drug

administration; page 9 of said response) and caselaw support relating to the significance of "suitable for" language in a claim (*Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 9890, 54 U.S.P.Q.2d 1227 (Fed. Cir. 2000), cert. denied, 531 U.S. 1183 (2001); page 11 of said response).

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the examiner does not believe that such action can be taken at this time, it is respectfully requested that she telephone Applicants' attorney at (908) 654-5000 in order to overcome any additional objections which she might have.

If there are any additional charges in connection with this requested amendment, the examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: June 28, 2005

Respectfully submitted,

By 

Harvey D. Cohen

Registration No.: 28,365
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorney for Applicants